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[54] **ELECTROCHEMICAL BIOSENSOR TEST STRIP**

60-173457 9/1985 Japan .
 60-173458 9/1985 Japan .
 60-173459 9/1985 Japan .

[75] Inventors: **William F. Crismore; Nigel A. Surridge, both of Indianapolis; Daniel R. McMinn, Fishers; Richard J. Bodensteiner, Indianapolis; Eric R. Diebold, Fishers; R. Dale Delk, Muncie; David W. Burke, Carmel; Jiaxiong Jason Ho, Carmel; Robert Kitchel Earl, Carmel; Brian A. Heald, Fishers, all of Ind.**

(List continued on next page.)

[73] Assignee: **Roche Diagnostics Corporation, Indianapolis, Ind.**

OTHER PUBLICATIONS

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324/692; 435/817**

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422/82.02, 76; 436/63, 149, 150, 151; 204/403,
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[56] **References Cited**

U.S. PATENT DOCUMENTS

4,224,125 9/1980 Nakamura et al.
4,254,083 3/1981 Columbus .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0 010 456 B1 4/1980 European Pat. Off. .
 0 080 304 A1 6/1983 European Pat. Off. .
 0 127 958 B1 12/1984 European Pat. Off. .
 0 136 362 B1 4/1985 European Pat. Off. .
 0 170 375 A2 2/1986 European Pat. Off. .
 0 206 218 A2 12/1986 European Pat. Off. .
 0 230 472 A1 8/1987 European Pat. Off. .
 0 359 831 A1 3/1990 European Pat. Off. .
 0 400 918 A1 12/1990 European Pat. Off. .
 0 537 761 A2 4/1993 European Pat. Off. .
 0 732 406 A1 9/1996 European Pat. Off. .

Williams et al., "Electrochemical-Enzymatic Analysis of Blood Glucose and Lactate," Analytical Chemistry, Monsanto Company (Everett, Massachusetts), vol. 42 (No. 1), pp. 118-121 (Jan. 1970).

Jonathan Lee Talbott, "Enzymatic Amperometry of Glucose," a Ph.D. Dissertation for The Pennsylvania State University, The Graduate School, Department of Chemistry (Jan. 1988).

Nankai et al., "disposable Glucose Sensor Using Hexacyanoferate(III) As A Mediator," Japanese Sensor Newsletter, Edison Sensor Technology Center, Case Western Reserve University (Cleveland, Ohio), vol. 3 (No. 1), pp. 16-20 (Mar. 1989).

Primary Examiner—Lyle A. Alexander
 Attorney, Agent, or Firm—Richard T. Knauer; Roche Diagnostics Corporation

[57] **ABSTRACT**

An electrochemical biosensor test strip with four new features. The test strip includes an indentation for tactile feel as to the location of the strips sample application port. The sample application port leads to a capillary test chamber, which includes a test reagent. The wet reagent includes from about 0.2% by weight to about 2% by weight polyethylene oxide from about 100 kilodaltons to about 900 kilodaltons mean molecular weight, which makes the dried reagent more hydrophilic and sturdier to strip processing steps, such as mechanical punching, and to mechanical manipulation by the test strip user. The roof of the capillary test chamber includes a transparent or translucent window which operates as a "fill to here" line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test. The test strip may further include a notch located at the sample application port. The notch reduces a phenomenon called "dose hesitation".

32 Claims, 5 Drawing Sheets